



Virginia
Regulatory
Town Hall

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Notice of Intended Regulatory Action (NOIRA) Agency Background Document

Agency name	Board of Medicine, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC85-130-10 et seq.
Regulation title	Regulations Governing the Practice of Licensed Midwives
Action title	Disclosures of risks to certain clients
Date this document prepared	5/21/09

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 36 (2006) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual*.

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

The purpose of the planned regulatory action is compliance with a legislative mandate for the adoption of regulations relating to disclosures of risk to certain patients. The law was amended by HB2163 (Chapter 646 of the 2009 Acts of the Assembly) to require the Board to adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall require midwives to “*disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child outside of a hospital or birthing center, as defined in subsection E of § 32.1-11.5, including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple gestation.*”

The amendments will set out the conditions or risks factors for which it is “appropriate” to disclose the options available for referral and consultation and to provide the evidence-based information to a client about risks associated with birth outside of a hospital or birthing center for women with certain conditions or clinical situations.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Medicine the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

- 1. To establish the qualifications for registration, certification or licensure in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.*
- 2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.*
- 3. To register, certify or license qualified applicants as practitioners of the particular profession or professions regulated by such board.*
- ...*
- 6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...*

A specific regulatory mandate for the Board of Medicine is found in § 54.1.2957.9:

§ [54.1-2957.9](#). *Regulation of the practice of midwifery.*

*The Board shall adopt regulations governing the practice of midwifery, upon consultation with the Advisory Board on Midwifery. The regulations shall (i) address the requirements for licensure to practice midwifery, including the establishment of standards of care, (ii) be consistent with the North American Registry of Midwives' current job description for the profession and the National Association of Certified Professional Midwives' standards of practice, except that prescriptive authority and the possession and administration of controlled substances shall be prohibited, (iii) ensure independent practice, (iv) **require midwives to disclose to their patients, when appropriate, options for consultation and referral to a physician and evidence-based information on health risks associated with birth of a child outside of a hospital or birthing center, as defined in subsection E of § [32.1-11.5](#), including but not limited to risks associated with vaginal births after a prior cesarean section, breech births, births by women experiencing high-risk pregnancies, and births involving multiple***

gestation, (v) provide for an appropriate license fee, and ~~(v)~~ (vi) include requirements for licensure renewal and continuing education. Such regulations shall not (a) require any agreement, written or otherwise, with another health care professional or (b) require the assessment of a woman who is seeking midwifery services by another health care professional.

License renewal shall be contingent upon maintaining a Certified Professional Midwife certification.

Need

Please detail the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. In addition, delineate any potential issues that may need to be addressed as the regulation is developed.

In Virginia, the Code requires that regulations to be consistent with the North American Registry of Midwives' (NARM) current job description for the profession. The NARM Position Paper on the Practice of Midwifery states that: "Certified Professional Midwives (CPMs) ...have demonstrated the knowledge and skills to provide full prenatal, birth, and postpartum care to low-risk women, to recognize deviations from normal, and to refer, consult, or transfer care if appropriate." The proposed regulation will be consistent with the NARM model in which midwives are expected to appropriately assess deviations from the normal and to disclose to clients those conditions or situations in which an out-of-hospital birth is not appropriate or those that may present certain risks to a woman or her baby.

The goal for the amended regulation would be to ensure that women are adequately informed of any risk for home birth associated with certain health conditions or prior birth history. Regulation of risk disclosure will require that women are adequately assessed and informed of the condition which presents increased risk for home birth and ensure that the choice of provider and birth setting are made with full disclosure of risk.

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed.

The proposed regulations will include the following:

- 1) A requirement that, upon initiation of care, the midwife review the woman's medical history, including records from prior pregnancies in order to identify pre-existing conditions that require disclosure of risk for home birth. The midwife will also be required to continually assess the pregnant woman in order to recognize conditions that may arise during the course of care that require disclosure of risk for home birth.

- 2) A listing of those factors or criteria that require disclosure that the client is not an appropriate candidate for an out-of-hospital birth, and a listing of those factors or criteria that require disclosure relating options for consultation and referral.
- 3) If the factors or criteria have been identified that may indicate health risks associated with birth of a child outside a hospital, a requirement for the midwife to provide evidence-based information on such risks. Such information would be specified by the Board for certain conditions and would include statements and evidence from both the medical and midwifery models of care.
- 4) A requirement for documentation in the client record of the assessment, the presence or absence of high risks, and, if appropriate the provision of disclosures and evidence-based information.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action. Also, please describe the process by which the agency has considered or will consider other alternatives for achieving the need in the most cost-effective manner.

There are no viable alternatives to the proposed regulatory action as it is mandated by the Code of Virginia.

In the development of regulations, the Advisory Board will consider standards adopted in other states. Many states require practice with a collaborating physician, referral to a physician at certain points in the pregnancy or whenever the woman presents with certain conditions, or prohibit a licensed midwife from providing care to women with specified high risk conditions. The proposed regulations implementing HB2163 will not contain such prohibitions or requirements, but will be focused on assessment and recognition of risks, provision of evidence-based information and disclosure to clients the options appropriate to those risks.

The model for proposed regulations in Virginia will likely be a state such as Oregon, in which midwifery has been widely-recognized and long-regulated. Oregon requires every licensed midwife to assess the appropriateness of an out-of-hospital birth for each client, taking into account the health and condition of the mother and fetus or baby according to two categories of risk assessment criteria. There are “absolute risk,” antepartum and intrapartum criteria indicating that the client or baby would be at extreme obstetrical or neonatal risk. In such situations, the midwife should disclose that the client is not an appropriate candidate for out-of-hospital birth. There are also “non-absolute” antepartum and intrapartum criteria indicating that a client may be at increased obstetric or neonatal risk, and consultation or referral may be necessary. If there are “non-absolute” risks present, the midwife should disclose those risks, present options for consultation and referral and document the client’s informed choice in the record.

Interested parties, from both medicine and midwifery, will have the opportunity to comment on the Notice of Intended Regulatory Action and to be involved in the development of language to implement the legislative mandate.

Public participation

Please indicate the agency is seeking comments on the intended regulatory action, to include ideas to assist the agency in the development of the proposal and the costs and benefits of the alternatives stated in this notice or other alternatives. Also, indicate whether a public hearing is to be held to receive comments on this notice.

The agency is seeking comments on the intended regulatory action, including but not limited to 1) ideas to assist in the development of a proposal, 2) the costs and benefits of the alternatives stated in this background document or other alternatives and 3) potential impacts of the regulation. The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so by mail, email or fax to Elaine Yeatts, Agency Regulatory Coordinator, 9960 Mayland Drive, (804) 527-4434 (fax) or Elaine.yeatts@dhp.virginia.gov or comment may be posted on the Regulatory Townhall at www.townhall.virginia.gov Written comments must include the name and address of the commenter. In order to be considered comments must be received by the last day of the public comment period.

In addition, the agency is seeking information on (1) the continued need for the regulation; (2) the complexity of the regulation; (3) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (4) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation.

A public hearing will be held after the Board has adopted proposed regulations. Notice of the hearing may be found on the Virginia Regulatory Town Hall website www.townhall.virginia.gov and can be found in the Calendar of Events section of the Virginia Register of Regulations. Both oral and written comments may be submitted at that time.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

The amendments have no impact on the institution of the family and family stability.